Case No.: DH-I-07-D100291

# DISTRICT OF COLUMBIA OFFICE OF ADMINISTRATIVE HEARINGS

825 North Capitol Street, NE, Suite 4150 Washington, DC 20002-4210 Telephone: (202) 442-9094 Fax: (202) 442-4789

DISTRICT OF COLUMBIA DEPARTMENT OF HEALTH Petitioner,

v. Case No.: DH-I-07-D100291

CVS PHARMACY #7120 Respondent.

## **FINAL ORDER**

### I. INTRODUCTION

This case arises under the Civil Infractions Act of 1985, as amended (D.C. Code, 2001 Ed. §§ 2-1801.01 *et seq.*) and D.C. Code, 2001 Ed. §§ 47-2885.10(a)(3)<sup>1</sup> and 47-2885.13(a);<sup>2</sup>

The Mayor may refuse the issuance or renewal, or may revoke, or may suspend for not more than 90 days, a license issued pursuant to this part for:

\* \* \*

(3) Selling, or offering for sale, adulterated or misbranded drugs or devices.

Drugs which may deteriorate shall at all times be stored under conditions specified on the label of the original container and in accordance with applicable District of Columbia or federal laws or regulations, and shall not be sold or dispensed after the expiration date designated on the label of the original container, and in accordance with applicable District of Columbia or federal laws or regulations.

<sup>&</sup>lt;sup>1</sup> D.C. Code, 2001 Ed. § 47-2885.10(a)(3) reads in pertinent part:

<sup>&</sup>lt;sup>2</sup> D.C. Code, 2001 Ed. § 47-2885.13(a) reads in full:

22 District of Columbia Municipal Regulations ("DCMR") 1502.1;<sup>3</sup> 22 DCMR 1908.2 and 1908.4;<sup>4</sup> and 22 DCMR 1901.6 (this provision was listed in the NOI as 22 DCMR 1909.6; however, the regulations were recodified in January 2008 and 1901.6 is the current citation).<sup>5</sup> By Notice of Infraction D100291, served on November 2, 2007, the Government charged Respondent, CVS Pharmacy #7120, with violating these provisions of the governing regulatory scheme by failing to clean the medication shelves and drug compounding area, mislabeling medicines that were prepared by the pharmacist for individual sale but then returned to stock (a "Return to Stock" violation (D.C. Code, 2001 Ed. §47-2885.10(a)(3)), storing expired drugs in active stock with unexpired drugs, and failing to complete required federal controlled substances form(s). The Government alleged that the violations occurred on October 30, 2007, at 1100 New Jersey Ave., SW and sought \$6,000 in fines. Respondent filed a denial on January 8, 2008, but on April 21, 2008, amended its plea to Admit with Explanation and sought a reduction in the proposed fines.

Every registrant shall keep records, maintain inventories and file reports in conformance with the requirements of federal law including the requirements prescribed under Part 1304, 21 CFR.

#### <sup>4</sup> 22 DCMR 1908 reads in pertinent part:

- (2) A pharmacy and all areas under the control of the pharmacy, including storage areas and restrooms, shall be maintained in a clean and sanitary condition free of infestation by rodents, birds, insects, and other vermin.
  - (4) All pharmacy equipment shall be kept clean and in good operating condition.

#### <sup>5</sup> 22 DCMR 1901.6 reads in full:

Drugs and medical devices with expired dating, or that are otherwise misbranded or adulterated, shall not be stored with currently dated products or those that are safe for their intended purposes, but shall be separated from active stock and so identified.

<sup>&</sup>lt;sup>3</sup> 22 DCMR 1502 reads in full:

On June 13, 2008, I consolidated this matter with nine other Notices of Infraction ("NOI"). OAH Rule 2919. However, I also separated non-"Return to Stock" violations for resolution in separate Final Orders. OAH Rule 2919.3. The Final Order concerning Return to Stock violations was issued on June 16, 2008. During a hearing on a different NOI issued to this Respondent, I granted the parties' request to stay this matter so they could attempt to settle this NOI and the nine others. They were unsuccessful and both parties have consented to this matter being resolved on the documents that were filed with the NOI and Respondent's pleas. Based on these documents and the entire record herein, I make the following findings of fact and conclusions of law.

#### II. FINDINGS OF FACT

- 1. On October 30, 2007, Pharmacy Inspector Kasimu-Graham inspected CVS store number 7120, located at 1100 New Jersey Ave., SW. During the investigation, Inspector Kasimu-Graham discovered that Respondent had failed to: a) clean the medication shelves and drug compounding area; b) segregate expired drugs from the active stock of unexpired drugs; and c) complete required federal controlled substances form(s).
- 2. Subsequent to the inspection, Respondent thoroughly cleaned and reorganized the pharmacy area of this store, and segregated expired prescription medicine from the active stock of unexpired drugs. As noted in the October 30, 2007, Pharmacy Inspection Report, Inspector Kasimu-Graham gave Respondent until November 1, 2007, to complete the required federal forms governing controlled substances to avoid a civil infraction. Respondent completed that form by the requisite deadline.

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#### III. DISCUSSION AND CONCLUSIONS OF LAW

The Government alleged that Respondent violated D.C. Code, 2001 Ed. § 47-2885.13(a), 22 DCMR 1502.1; 22 DCMR 1908.2 and 1908.4; and 22 DCMR 1901.6 by failing to clean the medication shelves and drug compounding area, storing expired drugs in active stock with unexpired drugs, and failing to complete required federal controlled substances form(s). Respondent admits the violations as alleged in the NOI, with the caveat that it made the mandated updates to the federal reports timely.

A violation of 22 DCMR 1908.2 and 1908.4 (failure to clean the medication shelves and pharmacy compounding area) is a Class 2 infraction punishable by a \$1,000 fine for a first offense. 16 DCMR 3201.1(b); 16 DCMR 3615.2(v). Respondent argued that a \$350 fine is appropriate, as the NOI does not specify the nature of the alleged "unsanitary conditions." A violation of D.C. Code, 2001 Ed. § 47-2885.13(a) (failing to segregate expired drugs from the active stock of unexpired drugs) is a Class 2 infraction punishable by a \$1,000 fine for a first offense. 16 DCMR 3201.1(b); 16 DCMR 3615.2(p). Respondent argued that a \$500 fine is appropriate, as it has corrected the problem. A violation of 22 DMCR 1502 (failure to keep records, maintain inventories and file reports in conformance with the requirements of federal law) is a Class 1 infraction punishable by a \$2,000 fine for a first offense. 16 DCMR 3201.1(a); 16 DCMR 3616.1(g). Respondent argued that the Inspector gave it until November 1, 2007, to update and complete the required records, which it did. Thus, Respondent argued that no fine should attach for this violation.

I conclude that Inspector Kasimu-Graham gave Respondent until November 1, 2007, to complete the required federal form and avoid a civil fine. Respondent met that deadline. I will

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suspend the fine associated with that violation. There are no mitigating circumstances concerning the other violations which warrant a reduction in the total fines. I impose a \$2,000 fine.

#### IV. ORDER

Therefore, based on the entire record herein, it is this 8th day of July 2008

ORDERED that Respondent CVS Store #7120 is LIABLE for violating D.C. Code, 2001 Ed. § 47-2885.13(a); 22 DCMR 1502.1; 22 DCMR 1908.2 and 1908.4; and 22 DCMR 1901.6 as charged in Notice of Infraction No. D100291; it is further

**ORDERED** that Respondent shall pay a fine in the amount of **TWO THOUSAND DOLLARS (\$2,000)** in accordance with the attached instructions within twenty (20) calendar days of the date of mailing of this Order (15 calendar days plus 5 days for service by mail pursuant, to D.C. Code, 2001 Ed. §§ 2-1802.04 and 2-1802.05); it is further

**ORDERED** that, if Respondent fails to pay the above amount in full within 20 calendar days of the date of mailing of this Order, by law, interest shall accrue on the unpaid amount at the rate of 1½ % per month or portion thereof, beginning with the date of this Order, pursuant to D.C. Code, 2001 Ed. § 2-1802.03(i)(1); it is further

**ORDERED** that failure to comply with the attached payment instructions and to remit a payment within the time specified will authorize the imposition of additional sanctions, including the suspension of Respondent's licenses or permits, pursuant to D.C. Code, 2001 Ed. § 2-1802.03(f), the placement of a lien on real or personal property owned by Respondent,

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pursuant to D.C. Code, 2001 Ed. § 2-1802.03(i), and the sealing of Respondent's business premises or work sites, pursuant to D.C. Code, 2001 Ed. § 2-1801.03(b)(7); it is further

**ORDERED** that the appeal rights of any person aggrieved by this Order are stated below.

July 8, 2008

/SS/

Jesse P. Goode

Administrative Law Judge